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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,262	08/10/2001	Menzo Jans E. Havenga	4509.1US	6584

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EXAMINER
WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,262	HAVENGA ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/10/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-28 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 and an election of species is required under 35 U.S.C. 121:

I. Claim 1-11, 24-25, and 27-28, drawn to an *in vivo* method of gene delivery comprising administering an adenoviral vector comprising a nucleic acid of interest to primary human chondrocytes and an *in vivo* genetically modified human chondrocytes comprising a nucleic acid encoding at least amino acid sequence that inhibits cartilage disease progression and/or at least one amino acid sequence that counteracts the loss of cartilage, classifiable in class 514, subclass 44.

II. Claim 1-11 and 24-25, drawn to an *in vitro* method of gene delivery comprising administering an adenoviral vector comprising a nucleic acid of interest to isolated human chondrocytes and isolated genetically modified human chondrocytes comprising a nucleic acid encoding at least amino acid sequence that inhibits cartilage disease progression and/or at least one amino acid sequence that counteracts the loss of cartilage, classifiable in class 424, subclass 93.21.

III. Claim 12-23 and 26, drawn to a gene delivery vehicle for delivering a nucleic acid of interest of a primary human chondrocyte, classifiable in class 435, subclass 320.1.

The inventions are distinct, each from the other because:

As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980), see MPEP 803.02, unity of invention exists for all species in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

In view of *In re Harnisch*, claims 1-11 and 24-25 lack unity of invention for the following reasons: 1) an ex vivo method of delivering a nucleic acid; 2) an in vivo method of delivering a nucleic acid; 3) an isolated genetically modified primary human chondrocytes; 4) an in vivo genetically modified primary human chondrocyte. An ex vivo method of delivering a nucleic acid does not have a common utility with an in vivo method of delivering a nucleic acid and both methods do not share a substantial structural feature disclosed as being essential for that utility. An ex vivo method encompasses isolating chondrocytes from a human; culturing said chondrocytes; genetically modifying chondrocytes with a gene delivery vehicle and re-introducing genetically modified chondrocytes into said human. An in vivo method encompasses delivering a gene delivery vehicle to a human primary human chondrocytes. Furthermore, the human chondrocytes listed above do not share a substantial structural feature. Therefore in view of In re Harnisch, claims 1-11 and 24-25 lack unity of invention and are separated into distinct groups as shown in Group I and II.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> products (distinct nucleic acid molecule), MPEP 802.01 states, "35 U.S.C. 121 quoted in the preceding section states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application, restriction is deemed to be proper between the distinct methods set forth in group I and II, because each of these groups appear to constitute a patentably distinct

inventions for the following reasons: Each group I and II comprises distinct methods and properties (in vivo method or ex vivo method), wherein each method encompasses a product that can be used for different and distinct purposes using materially different and distinct products. Moreover, each method in each group does not require any of the particulars recited in each of the other methods. Therefore, each group I and II is distinct from each other.

Inventions III and I, II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene delivery vehicle set forth in Group III, can be used in a material distinct process as set forth in Groups I or II.

If applicants elect either group I or group II, the applicants are further required to elect a species from the following:

This application contains claims directed to the following patentably distinct species of the claimed invention: a nucleic acid of interest listed on page 5 of the as-filed specification (e.g. bone morphogenesis protein).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 and 24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, if applicants elect from Group I or II applicants further required to elect a species from the following:

Claim 2 is generic to a plurality of disclosed patentably distinct species comprising to a recombinant adenovirus comprises at least one deletion in the E3 region where a nucleic acid of interest is inserted; a recombinant adenovirus comprises at least one deletion in the E2 region where a nucleic acid of interest is inserted; a recombinant adenovirus comprises at least one deletion in the E4 region where a nucleic acid of interest is inserted; or a recombinant adenovirus comprises at least one deletion in the E2 and E4 region where a nucleic acid of interest is inserted in claims 8 and 9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 4 is generic to a plurality of disclosed patentably distinct species comprising a fiber protein derived from adenovirus type 16, 35 and/or 51 in claim 5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Furthermore, if applicants elect from Group III applicants further required to elect a species from the following:

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising a fiber protein derived from adenovirus type 16, 35 and/or 51 in claim 18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 15 is generic to a plurality of disclosed patentably distinct species comprising to a recombinant adenovirus comprises at least one deletion in the E3 region where a nucleic acid of interest is inserted; a recombinant adenovirus comprises at least one deletion in the E2 region where a nucleic acid of interest is inserted; a recombinant adenovirus comprises at least one deletion in the E4 region where a nucleic acid of interest is inserted; or a recombinant adenovirus comprises at least one deletion in the E2 and E4 region where a nucleic acid of interest is

inserted in claims 21 and 22. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Group II or Group III and vice versa, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635
10/31/02

DAVE T. NGUYEN
PRIMARY EXAMINER